

108TH CONGRESS  
1ST SESSION

# S. 376

To amend the Public Health Service Act to promote organ donation and facilitate interstate linkage and 24-hour access to State donor registries, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

FEBRUARY 12, 2003

Mr. DURBIN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Public Health Service Act to promote organ donation and facilitate interstate linkage and 24-hour access to State donor registries, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as “The Donor Outreach, Net-  
5       work, and Timely Exchange Act” or the “DONATE Act”.

1 **SEC. 2. AMENDMENT TO THE PUBLIC HEALTH SERVICE**  
2 **ACT.**

3 Part H of title III of the Public Health Service Act  
4 (42 U.S.C. 273 et seq.) is amended by inserting after sec-  
5 tion 371 the following:

6 **“SEC. 371A. NATIONAL ORGAN AND TISSUE DONOR REG-**  
7 **ISTRY RESOURCE CENTER.**

8 “(a) IN GENERAL.—The Secretary, acting through  
9 the Administrator of the Health Resources and Services  
10 Administration, shall establish a National Organ and Tis-  
11 sue Donor Registry Resource Center (referred to in this  
12 section as the ‘Center’).

13 “(b) DUTIES.—The Center established under sub-  
14 section (a) shall—

15 “(1) advance the development, expansion, and  
16 evaluation of State donor registries;

17 “(2) facilitate timely access to and exchange of  
18 accurate donor information between State registries  
19 on a 24-hour a day basis;

20 “(3) develop consensus guidelines on a standard  
21 registry model, including whether or not such reg-  
22 istries should include living donor information, that  
23 represents best practices, including—

24 “(A) the core functions and content of a  
25 registry;

1 “(B) clear legal and ethical standards for  
2 minimum levels of information necessary to es-  
3 tablish informed consent;

4 “(C) standardized, legally verifiable con-  
5 sent documentation;

6 “(D) privacy protections, including guide-  
7 lines for accessing the registry database;

8 “(E) data exchange protocols and stand-  
9 ards; and

10 “(F) methods to legally enforce the wishes  
11 of the donor;

12 “(4) provide technical assistance to the States  
13 for the establishment and operation of State reg-  
14 istries, including assistance in developing model leg-  
15 islation for State registries; and

16 “(5) maintain a registry information clearing-  
17 house to collect, synthesize, and disseminate best  
18 practices information about donor registries, includ-  
19 ing maintaining a web site.

20 “(c) AUTHORIZATION OF APPROPRIATIONS.—There  
21 is authorized to be appropriated to carry out this section,  
22 \$5,000,000 for each of the fiscal years 2004 through  
23 2008.

1 **“SEC. 371B. GRANTS FOR STATE ORGAN AND TISSUE**  
 2 **DONOR REGISTRIES.**

3 “(a) PROGRAM AUTHORIZED.—The Secretary shall  
 4 award grants or cooperative agreements to eligible entities  
 5 to support the development, enhancement, expansion, and  
 6 evaluation of State organ and tissue donor registries.

7 “(b) ELIGIBLE ENTITY.—In this section, the term  
 8 ‘eligible entity’ means a State.

9 “(c) USE OF FUNDS.—An eligible entity that receives  
 10 a grant or cooperative agreement under subsection (a)  
 11 shall—

12 “(1) provide for authorization under State law  
 13 of the registry;

14 “(2) establish benchmarks for improvement in  
 15 organ donation in the State;

16 “(3) at a minimum, make registries available to  
 17 organ procurement organizations and to other State  
 18 agencies 24 hours, 7 days a week and without a fee;

19 “(4) include provisions that protect the privacy  
 20 of donors; and

21 “(5) include legal protections for individuals  
 22 complying with the law, including those who carry  
 23 out advance directives and organ, tissue, and eye  
 24 procurement.

25 “(d) APPLICATION.—An entity that desires a grant  
 26 or cooperative agreement under subsection (a) shall sub-

1 mit an application to the Secretary at such time, in such  
2 manner, and containing such information as the Secretary  
3 may reasonably require.

4 “(e) REPORT.—An eligible entity that receives a  
5 grant or cooperative agreement under subsection (a) shall  
6 prepare and submit a report to the Secretary that de-  
7 scribes the manner in which such entity has used amounts  
8 received through a grant under this section and assesses  
9 initiatives that may be replicated in other States.

10 “(f) AUTHORIZATION OF APPROPRIATIONS.—There  
11 is authorized to be appropriated to carry out this section,  
12 \$10,000,000 for each of the fiscal years 2004 through  
13 2008.

14 **“SEC. 371C. ADVISORY TASK FORCE.**

15 “(a) IN GENERAL.—The Secretary shall establish an  
16 advisory task force to study State registries and make rec-  
17 ommendations to Congress regarding such registries.

18 “(b) MEMBERSHIP.—The task force shall be com-  
19 posed of 10 members of whom—

20 “(1) at least 1 member shall be a physician  
21 with experience performing transplants;

22 “(2) at least 1 member shall have experience in  
23 organ procurement;

1           “(3) at least 2 members shall be representatives  
2           of organizations with experience conducting national  
3           awareness campaigns and donor outreach;

4           “(4) at least 2 members shall be representatives  
5           of States with existing donor registries;

6           “(5) at least 1 member shall have experience  
7           with national information systems where coordina-  
8           tion occurs with State-based systems; and

9           “(6) at least 1 member shall represent donor  
10          families, transplant recipients, and those awaiting  
11          transplantation.

12          “(c) TERM.—Members shall be appointed for 3-year  
13          rotating terms. Any vacancy in the task force shall not  
14          affect its powers, but shall be filled in the same manner  
15          as the original appointment.

16          “(d) INITIAL MEETING.—Not later than 30 days  
17          after the date on which all members of the task force have  
18          been appointed, the task force shall hold its first meeting.

19          “(e) MEETINGS.—The task force shall meet at the  
20          call of the Chairman who shall be selected by the Sec-  
21          retary.

22          “(f) COMPENSATION.—Each member of the task  
23          force shall not receive compensation for services provided  
24          under this section.

1       “(g) TRAVEL EXPENSES.—The members of the task  
2 force shall be allowed travel expenses, including per diem  
3 in lieu of subsistence, at rates authorized for employees  
4 of agencies under subchapter I of chapter 57 of title 5,  
5 United States Code, while away from their homes or reg-  
6 ular places of business in the performance of services for  
7 the task force.

8       “(h) ADMINISTRATIVE SUPPORT.—The Secretary  
9 shall ensure that the task force is provided with adminis-  
10 trative support or any other technical assistance that such  
11 task force needs in carrying out its duties.

12       “(i) PERMANENT COMMITTEE.—Section 14 of the  
13 Federal Advisory Committee Act shall not apply to the  
14 task force established under this section.

15       “(j) REPORT.—Not later than 1 year after the date  
16 of enactment of this section, and in the subsequent year  
17 as well, the task force established under subsection (a)  
18 shall prepare and submit to Congress a report regarding  
19 the status of State registries, current best practices, rec-  
20 ommendations to increase the number and quality of State  
21 registries, and recommendations regarding the merits of  
22 a national database or ways to improve linkages between  
23 State registries and consider and make recommendations  
24 regarding whether any Federal funds for the establish-  
25 ment of new registries should be limited to State agency

1 processes that are linked to the ability to make a legally  
 2 binding gift.

3 **“SEC. 371D. EXPENSES INCURRED TOWARD LIVING ORGAN**  
 4 **DONATION.**

5 “(a) IN GENERAL.—The Secretary may award grants  
 6 to eligible entities to pay for travel, subsistence, and other  
 7 necessary nonmedical miscellaneous expenses related to  
 8 living organ donation by any donating individual.

9 “(b) DEFINITIONS.—In this section:

10 “(1) DONATING INDIVIDUAL.—The term ‘do-  
 11 nating individual’ means any individual who is mak-  
 12 ing, or in good faith plans to make, a living donation  
 13 of his or her organs.

14 “(2) ELIGIBLE ENTITY.—The term ‘eligible en-  
 15 tity’ means a State, transplant center, qualified  
 16 organ procurement organization under section 371,  
 17 or other public or private entity.

18 “(3) NECESSARY NONMEDICAL MISCELLANEOUS  
 19 EXPENSES.—The term ‘necessary nonmedical mis-  
 20 cellaneous expenses’ means such necessary nonmed-  
 21 ical miscellaneous expenses as the Secretary deems  
 22 appropriate.

23 “(c) PREFERENCE.—Preference shall be given to in-  
 24 tended recipients or donors of organs with incomes not  
 25 exceeding \$60,000 (as adjusted for fiscal year 2004 and



1 subsequent fiscal years to offset the effects of inflation oc-  
 2 ccurring after the beginning of fiscal year 2003).

3 “(d) USE OF FUNDS.—

4 “(1) IN GENERAL.—An eligible entity that re-  
 5 ceives a grant under subsection (a) shall use funds  
 6 received through such grant to pay for travel, sub-  
 7 sistence, and other necessary nonmedical miscella-  
 8 neous expenses of any donating individual.

9 “(2) FAMILY.—An eligible entity that receives a  
 10 grant under subsection (a) may use funds received  
 11 through such grant to pay for travel, subsistence,  
 12 and other necessary nonmedical miscellaneous ex-  
 13 penses of 1 or more family members of any donating  
 14 individual to accompany the donating individual in  
 15 making the living donation.

16 “(3) PROHIBITION.—An eligible entity shall not  
 17 pay the travel, subsistence, and other necessary non-  
 18 medical miscellaneous expenses of a donating indi-  
 19 vidual if payment has been made, or can reasonably  
 20 be expected to be made, with respect to such ex-  
 21 penses—

22 “(A) under any State compensation pro-  
 23 gram, under an insurance policy, or under any  
 24 Federal or State health benefits program;

1                   “(B) by an entity that provides health  
2                   services on a prepaid basis; or

3                   “(C) by the recipient of the organ.

4           “(e) AUTHORIZATION OF APPROPRIATIONS.—There  
5 is authorized to be appropriated to carry out this section,  
6 \$15,000,000 for fiscal year 2004, and such sums as may  
7 be necessary for each of the fiscal years 2005 through  
8 2008.

9   **“SEC. 371E. ORGAN DONATION PUBLIC AWARENESS PRO-**  
10                   **GRAM.**

11           “(a) NATIONAL PROGRAM.—The Secretary shall es-  
12 tablish a public education program to increase awareness  
13 about organ donation and the need to provide for an ade-  
14 quate rate of such donations.

15           “(b) GRANTS TO ENTITIES.—The Secretary may  
16 award grants to public and nonprofit private entities to  
17 carry out studies and demonstration projects with respect  
18 to providing for an adequate rate of organ donation.

19           “(c) GRANTS TO STATES.—

20                   “(1) IN GENERAL.—The Secretary may award  
21 grants to States to establish programs designed to  
22 increase awareness regarding organ donation and  
23 the number of organ donors within the State, includ-  
24 ing living donors.

1           “(2) USE OF FUNDS.—A State that receives a  
2           grant under paragraph (1) may use funds received  
3           through such grant to—

4                   “(A) work in a partnership with other pub-  
5           lic agencies or private sector institutions for  
6           education and awareness efforts, information  
7           dissemination, activities pertaining to the State  
8           organ donor registry, and other innovative do-  
9           nation specific initiatives, including living dona-  
10          tion;

11                   “(B) establish yearly benchmarks for im-  
12          provement in organ donation rates in the State;  
13          and

14                   “(C) develop, enhance or expand a State  
15          donor registry, which shall be available to organ  
16          procurement organizations and other State  
17          agencies upon a search request 24 hours, 7  
18          days a week.

19           “(3) APPLICATION.—A State shall submit an  
20          application at such time, in such manner, and con-  
21          taining such information as the Secretary may rea-  
22          sonably require.

23           “(4) REPORT.—A State that receives a grant  
24          under paragraph (1) shall prepare and submit to the  
25          Secretary a report on an annual basis that describes

1 the State's use of funds received under this sub-  
2 section, and assesses the use of such funds and any  
3 initiatives for potential replication in other States.

4 “(d) REPORT.—The Secretary shall annually submit  
5 to the Congress a report on the activities carried out under  
6 this section, including provisions describing the extent to  
7 which the activities have affected the rate of organ dona-  
8 tion.

9 “(e) AUTHORIZATION OF APPROPRIATIONS.—There  
10 is authorized to be appropriated to carry out this section,  
11 \$5,000,000 for fiscal year 2004, and such sums as may  
12 be necessary for each of the fiscal years 2005 through  
13 2008.”.

14 **SEC. 3. CONGRESSIONAL MEDAL.**

15 (a) IN GENERAL.—The Secretary of the Treasury  
16 shall design and strike a bronze medal with suitable em-  
17 blems, devices, and inscriptions, to be determined by the  
18 Secretary of the Treasury, to commemorate organ donors  
19 and their families.

20 (b) ELIGIBILITY.—Any organ donor, or the family or  
21 family member of any organ donor, shall be eligible for  
22 a medal described in subsection (a).

23 (c) DOCUMENTATION.—The Secretary of Health and  
24 Human Services shall direct the entity holding the Organ

1 Procurement and Transplantation Network (hereafter in  
2 this Act referred to as “OPTN”) to contract to—

3 (1) establish an application procedure requiring  
4 the relevant organ procurement organization, as de-  
5 scribed in section 371(b)(1) of the Public Health  
6 Service Act (42 U.S.C. 273(b)(1)), through which an  
7 individual or their family made an organ donation,  
8 to submit to the OPTN contractor documentation  
9 supporting the eligibility of that individual or their  
10 family to receive a medal described in subsection (a);  
11 and

12 (2) determine, through the documentation pro-  
13 vided, and, if necessary, independent investigation,  
14 whether the individual or family is eligible to receive  
15 a medal described in subsection (a).

16 (d) DELIVERY TO THE SECRETARY OF HEALTH AND  
17 HUMAN SERVICES.—The Secretary of the Treasury shall  
18 deliver medals struck pursuant to this Act to the Secretary  
19 of Health and Human Services.

20 (e) DELIVERY TO ELIGIBLE RECIPIENTS.—The Sec-  
21 retary of Health and Human Services shall direct the  
22 OPTN contractor to arrange for the presentation to the  
23 relevant organ procurement organization all medals struck  
24 pursuant to this Act to individuals or families that the

1 OPTN contractor has determined to be eligible to receive  
2 medals under this Act.

3 (f) LIMITATION.—

4 (1) IN GENERAL.—Except as provided in para-  
5 graph (2), only 1 medal may be presented to a fam-  
6 ily under subsection (b). Such medal shall be pre-  
7 sented to the donating family member, or in the case  
8 of a deceased donor, the family member who signed  
9 the consent form authorizing, or who otherwise au-  
10 thorized, the donation of the organ involved.

11 (2) EXCEPTION.—In the case of a family in  
12 which more than 1 member is an organ donor, the  
13 OPTN contractor may present an additional medal  
14 to each such organ donor or their family.

15 (g) DUPLICATE MEDALS.—

16 (1) IN GENERAL.—The Secretary of Health and  
17 Human Services or the OPTN contractor may pro-  
18 vide duplicates of the medal described in subsection  
19 (a) to any recipient of a medal under subsection (e),  
20 under such regulations as the Secretary of Health  
21 and Human Services may issue.

22 (2) LIMITATION.—The price of a duplicate  
23 medal shall be sufficient to cover the cost of such  
24 duplicates.

1 (h) NATIONAL MEDALS.—The medals struck pursu-  
2 ant to this section are national medals for purposes of sec-  
3 tion 5111 of title 31, United States Code.

4 (i) GENERAL WAIVER OF PROCUREMENT REGULA-  
5 TIONS.—No provision of law governing procurement or  
6 public contracts shall be applicable to the procurement of  
7 goods or services necessary for carrying out the provisions  
8 of this Act.

9 (j) SOLICITATION OF DONATIONS.—

10 (1) IN GENERAL.—The Secretary of the Treas-  
11 ury may enter into an agreement with the OPTN  
12 contractor to collect funds to offset expenditures re-  
13 lating to the issuance of medals authorized under  
14 this section.

15 (2) PAYMENT OF FUNDS.—

16 (A) IN GENERAL.—Except as provided in  
17 subparagraph (B), all funds received by the  
18 Organ Procurement and Transplantation Net-  
19 work under paragraph (1) shall be promptly  
20 paid by the Organ Procurement and Transplan-  
21 tation Network to the Secretary of the Treas-  
22 ury.

23 (B) LIMITATION.—Not more than 5 per-  
24 cent of any funds received under paragraph (1)  
25 shall be used to pay administrative costs in-

1           curred by the OPTN contractor as a result of  
2           an agreement established under this section.

3           (3) NUMISMATIC PUBLIC ENTERPRISE FUND.—

4       Notwithstanding any other provision of law—

5           (A) all amounts received by the Secretary  
6           of the Treasury under paragraph (2)(A) shall  
7           be deposited in the Numismatic Public Enter-  
8           prise Fund, as described in section 5134 of title  
9           31, United States Code; and

10          (B) the Secretary of the Treasury shall  
11          charge such fund with all expenditures relating  
12          to the issuance of medals authorized under this  
13          section.

14          (4) START-UP COSTS.—A 1-time amount not to  
15          exceed \$55,000 shall be provided to the OPTN con-  
16          tractor to cover initial start-up costs. The amount  
17          will be paid back in full within 3 years of the date  
18          of the enactment of this Act from funds received  
19          under paragraph (1).

20          (5) NO NET COST TO THE GOVERNMENT.—The  
21          Secretary of the Treasury shall take all actions nec-  
22          essary to ensure that the issuance of medals author-  
23          ized under subsection (a) results in no net cost to  
24          the Government.

25          (k) DEFINITIONS.—In this section:



1           (1) ORGAN.—The term “organ” means the  
 2           human kidney, liver, heart, lung, pancreas, and any  
 3           other human organ (other than corneas and eyes)  
 4           specified by regulation of the Secretary of Health  
 5           and Human Services or the OPTN contractor.

6           (2) ORGAN PROCUREMENT AND TRANSPLAN-  
 7           TATION NETWORK.—The term “Organ Procurement  
 8           and Transplantation Network” means the Organ  
 9           Procurement and Transplantation Network estab-  
 10          lished under section 372 of the Public Health Serv-  
 11          ice Act (42 U.S.C. 274).

12          (l) SUNSET PROVISION.—This section shall be effec-  
 13          tive during the 5-year period beginning on the date of the  
 14          enactment of this Act.

15   **SEC. 4. IOM REPORT.**

16          (a) IN GENERAL.—The Secretary shall enter into a  
 17          contract with the Institute of Medicine to conduct an eval-  
 18          uation of the organ donation practices of organ procure-  
 19          ment organizations, States, other countries, and other ap-  
 20          propriate organizations that have achieved a higher than  
 21          average organ donation rate.

22          (b) BARRIERS.—In conducting the evaluation under  
 23          subsection (a), the Institute of Medicine shall examine ex-  
 24          isting barriers to organ donation.

1 (c) REPORT.—Not later than 18 months after the  
 2 date of enactment of this section, the Institute of Medicine  
 3 shall submit to the Secretary of Health and Human Serv-  
 4 ices a report concerning the evaluation conducted under  
 5 this section. Such report shall include recommendations  
 6 for administrative actions and, if necessary, legislation in  
 7 order to replicate the best practices identified in the eval-  
 8 uation and to otherwise increase organ donation and pro-  
 9 curement rates.

10 **SEC. 5. ESTABLISHMENT OF PROGRAM OF GRANTS RE-**  
 11 **GARDING HOSPITAL ORGAN DONATION CO-**  
 12 **ORDINATORS.**

13 Part H of title III of the Public Health Service Act  
 14 (42 U.S.C. 273 et seq.) is amended by inserting after sec-  
 15 tion 374 the following:

16 **“SEC. 374A. GRANTS REGARDING HOSPITAL ORGAN DONA-**  
 17 **TION COORDINATORS.**

18 “(a) IN GENERAL.—

19 “(1) IN GENERAL.—The Secretary may award  
 20 grants to qualifying organ donation entities to estab-  
 21 lish programs coordinating organ donation activities  
 22 of eligible hospitals, including coordinating with  
 23 qualified organ procurement organizations under  
 24 section 371. Such activities shall be coordinated to

1       increase the rate of organ donations for such hos-  
2       pitals.

3           “(2) ELIGIBLE HOSPITAL.—For purposes of  
4       this section, an eligible hospital is a public or non-  
5       profit private hospital that performs significant trau-  
6       ma care, or a public or nonprofit private hospital or  
7       consortium of such hospitals that serves a popu-  
8       lation base of not fewer than 200,000 individuals.

9           “(3) QUALIFYING ORGAN DONATION ENTITY.—  
10       In this section, the term ‘qualifying organ donation  
11       entity’ means—

12               “(A) an eligible hospital; or

13               “(B) a qualified organ procurement orga-  
14       nization under section 371.

15       “(b) PREFERENCE IN MAKING GRANTS.—In making  
16       grants under subsection (a), the Secretary shall give pref-  
17       erence to an applicant if the Secretary determines that  
18       the probable result of such a grant would be a significant  
19       increase in the rate of organ donation for the eligible hos-  
20       pital involved.

21       “(c) ADMINISTRATION OF COORDINATION PRO-  
22       GRAM.—A condition for the receipt of a grant under sub-  
23       section (a) is that the applicant involved agree that the  
24       program under such subsection will be carried out joint-  
25       ly—

1           “(1) by representatives from the eligible hos-  
 2           pital and the qualified organ procurement organiza-  
 3           tion with respect to which the grant is made; and

4           “(2) by such other entities as the representa-  
 5           tives referred to in paragraph (1) may designate.

6           “(d) EVALUATIONS; REPORT TO CONGRESS.—

7           “(1) EVALUATIONS.—The Secretary shall, di-  
 8           rectly or through contracts with public or private en-  
 9           tities, provide for annual evaluations of programs  
 10          carried out pursuant to subsection (a) in order to  
 11          determine the extent to which the programs have in-  
 12          creased the rate of organ donation for the eligible  
 13          hospitals involved.

14          “(2) REPORT.—Not later than 1 year after the  
 15          date on which amounts are first appropriated pursu-  
 16          ant to subsection (f), and annually thereafter, the  
 17          Secretary shall submit to the appropriate committees  
 18          of the Congress a report that summarizes evalua-  
 19          tions under paragraph (1).

20          “(e) MATCHING REQUIREMENT.—The Secretary may  
 21          not award a grant to a qualifying organ donation entity  
 22          under this section unless such entity agrees that, with re-  
 23          spect to costs to be incurred by the entity in carrying out  
 24          activities for which the grant was awarded, the entity shall  
 25          make available (directly or through donations from public

1 or private entities) non-Federal contributions in an  
 2 amount equal to 30 percent of the grant awarded to such  
 3 entity.

4 “(f) FUNDING.—

5 “(1) AUTHORIZATION OF APPROPRIATIONS.—

6 For the purpose of carrying out this section, there  
 7 are authorized to be appropriated \$3,000,000 for  
 8 fiscal years 2004 through 2007.

9 “(2) ALLOCATION.—Of the amounts appro-  
 10 priated under paragraph (1) for a fiscal year, the  
 11 Secretary shall reserve 50 percent for grants under  
 12 subsection (a) to qualifying organ donation entities  
 13 described in paragraph (3)(A) of such subsection  
 14 and 50 percent for grants under subsection (a) to  
 15 qualifying organ donation entities described in para-  
 16 graph (3)(B) of such subsection.”.

17 **SEC. 6. LIMITATION.**

18 Nothing in this Act shall affect organ and tissue allo-  
 19 cation. Standard State and national practices that deter-  
 20 mine the appropriate procurement organization for obtain-  
 21 ing consent for an individual organ or tissue donation shall  
 22 continue to apply to such determinations.

○